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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,939	12/04/2006	Alexander Abbas	GNE-0267 R1-1	3703
77845	7590	05/26/2009		
Goodwin Procter LLP Attn: Patent Administrator 135 Commonwealth Drive Menlo Park, CA 94025-1105			EXAMINER LI, RUIXIANG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 05/26/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,939	Applicant(s) ABBAS ET AL.	
	Examiner RUIXIANG LI	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 11-16 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/20/2006, 12/04/2006, 12/09/2008</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Alignment</u> . |

DETAILED ACTION

Restriction/Election

1. Applicant's election without traverse of claims 11-16, drawn to an antibody which specifically binds to the polypeptide of SEQ ID NO: 2120 in the reply filed on 07/11/2008 is acknowledged.
2. Applicants preliminary amendment filed on 07/11/2008 and 11/09/2008 have been entered. Claims 8 and 11-16 are pending. Claims 11-16 are currently under consideration. Claim 8 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Objection to the Title

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

4. The information disclosure statements filed on 03/20/2006, 12/04/2006, and 12/09/2008 have been considered by the Examiner and a signed copy of the form PTO-1449 is attached to the office action.

Drawings

5. The specification refers to figures (beginning at page 89). It is noted that, however, Applicants have not submitted any drawings yet.

Claim Rejections —35 U.S.C. § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 11 is rejected under 35 U.S.C. 101 because the claims invention is directed non-statutory subject matter.

Claim 11, as written, does not sufficiently distinguish over an antibody that exists naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified”. See MPEP 2105.

8. Claims 11-16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 11-16 are drawn to an antibody which specifically binds to a polypeptide of SEQ ID NO: 2120. The claimed invention is not supported by either a

specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a “real world” context of use for the claimed invention which does not require further research.

The instant specification discloses the polypeptide of SEQ ID NO: 2120 (or PRO220 polypeptide) and antibodies against the polypeptide. Nonetheless, the instant disclosure fails to provide sufficient information or evidence on the specific biological functions or physiological significance of the molecules of the present invention and fails to disclose a patentable utility for the claimed invention.

First, the invention lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification’s disclosure of the properties of a material. While the sequence of SEQ ID NO: 2120 is known in the prior art (see, e.g., Hillman et al. (US 6,168,920 B1, Jan. 2, 2001), the sequence and prior art search does not reveal that the polypeptide of SEQ ID NO: 2120 or an antibody that binds to the polypeptide has any well-established biological functions or any physiological significance. No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the claimed invention.

Secondly, the present invention does not disclose a specific and substantial utility. In Example 1 of microarray analysis of stimulated T cells, the specification discloses that the polypeptide of SEQ ID NO: 2120 show differential expression in isolated stimulated CD⁺ T helper cells as compared to unstimulated CD⁺ T help cells

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or isolated resting CD+ T helper cells (page 78, the 1st paragraph to 2nd paragraph). The specification asserts that this data demonstrates that the polypeptide of the present invention is useful not only as a diagnostic marker for the presence of one or more immune disorders, but also serve as a therapeutic target for the treatment of these immune disorders (page 78, the 1st paragraph). These asserted utilities are not specific and substantial because they do not identify or reasonably confirm a “real world” context of use. Such a disclosure is not sufficient to establish either a causative link or correlation between the polypeptide of SEQ ID NO: 2120 and a specific immune disorder. Clearly, further research would be required to identify a particular immune disorder that is associated with the polypeptide of SEQ ID NO: 2120 or that can be treated with the polypeptide of SEQ ID NO: 2120. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

Accordingly, the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility.

9. Claims 11-16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections—35 USC § 112, 2nd paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11, 13, and 16 are indefinite because they refer amino acid sequences to figures. The amino acid sequences should be clearly identified by a sequence identifier (SEQ ID NO).

Claim 15 is indefinite because it recites “a therapeutically effective amount”. Since the specification does not disclose treatment a particular disease and does not define the term, the claim is indefinite.

Claim Rejections—35 USC § 102 (b)

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 11-16 are rejected under 35 U.S.C. 102 (b) as being anticipated by Hillman et al. (US 6,168,920 B1, Jan. 2, 2001).

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Hillman et al. teach a polypeptide that is 100% identical to the polypeptide of SEQ ID NO: 2120 of the present invention (see attached sequence alignment). Hillman et al. teach an antibody that binds to the polypeptide, such as a monoclonal antibody, a single chain antibody (column 22, the 2nd paragraph), and a humanized antibody (column 22, lines 59-63). Hillman et al. also teach a composition comprising the antibody and a pharmaceutically acceptable carrier (column 25, the 3rd paragraph) and a therapeutically effective dose of antibodies (column 26, last paragraph). The antibodies are necessarily stored in a container (column 38, beginning at line 21). The label on the container in claim 16 is not given any patentable weight. Thus, the teachings of Hillman et al. meet the limitations of claims 11-16.

Claim Objection—Minor Informalities

14. Claims 1-8, 10, and 11 are objected to because of the following minor informalities:
- (i). claims 11, 13, and 16 depend from non-elected claim 8; (ii). claims 11-16 recite non-elected subject matter. Appropriate correction is required.

Conclusion

15. No claims are allowed.

Advisory Information

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/

Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.

May 22, 2009